REMARKS/ARGUMENTS

The rejections presented in the Office Action dated December 8, 2009 (hereinafter Office Action) have been considered. Claims 1, 4, 6, 13-15, 18, 20, 21, 29, 30, 33, 36, 39-41, 48-50, 53, 55, 58, 60, 63, and 64 remain pending in the application. Claim 64 is amended herein to address an error in the claim. This amendment should be entered because it clarifies the claim but does not change the scope of the claim. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 13-15, 18, 20, 33, 36, 39, 48-50, 53, 55, 60, and 63-64 are rejected based on 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2005/0038478 by Klepfer et al. (hereinafter "Klepfer") in view of U.S. Patent No. 7,031,773 to Levine et al. (hereinafter "Levine"). Claims 4, 6, 21, 29-30, 40-41, and 58 are also rejected based on 35 U.S.C. §103(a) as being unpatentable over Klepfer in view of Levine

The rejection does not account for all elements of the independent claims. For example, independent claim 1 states "disabling atrial [antitachycardia pacing (ATP)] therapy delivery and delivering a non-atrial tracking pacing therapy in response to the measured impedance deviating from the impedance threshold by a predetermined factor indicating dislodgement of the atrial lead." Independent claim 36 is also directed to disabling atrial antitachycardia pacing therapy delivery and delivering a non-atrial tracking pacing therapy in response to measured impedance indicating dislodgement of an atrial lead. In addressing this subject matter, the Office Action states:

> Klepfer discloses an Anti-tachycardia Pacing therapy that checks to see if a beat is an abnormal evoked response, if so it then checks for a lead related condition and if a condition is found it disables the ATP therapy (e.g. ¶¶80, 85, 111; Fig. 6). Klepfer discloses the claimed invention including that the lead related condition is checked using the impedance (e.g. ¶¶80, 85, 111). Klepfer further discloses that when the ATP therapy is disabled the system it adjusts the therapy (e.g. ¶85). Klepfer further discloses that one of the many therapies available in the system are non-atrial tracking pacing therapies such as VVI and DDI therapies (e.g. ¶ 59, Claims 12 and 22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the therapy that the system

> switches to after ATP therapy as taught by Klepfer e.g. ¶85, with one of the other therapies as disclosed by Klepfer that does not require an atrial sensing lead (Pages 2-3).

The above basis for the rejection is improper for several reasons. For example, after mentioning that Klepfer references VVI and DDI therapies, the Office Action then implies that Klepfer discloses switching therapies in response to detection of a lead related condition ("It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the therapy that the system switches to after ATP therapy as taught by Klepfer e.g. ¶85, with one of the other therapies as disclosed by Klepfer" (Id., emphasis added). Klepfer does not disclose switching therapies in response to detection of a lead condition. For example, paragraphs [0080] and [0085], cited in the above excerpt from the rejection, state:

> If the ARI following a stimulation pulse is substantially different from the ARI expected of a normal evoked response to the pulse, the stimulation therapy may be adjusted or temporarily withheld. ([0080] in part; emphasis added).
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> . . .
>
> Additional diagnostic procedures known in the art may be performed at step 485 after detecting an abnormal beat, such as, but not limited to, analyzing the cardiac rhythm for detecting an arrhythmia or pro-arrhythmic state, diagnosing a lead-related problem, or verifying appropriate sensing thresholds. After a temporary withholding of therapy for one or more beats, or after adjusting the stimulation therapy, for example by changing stimulation electrodes, stimulation pulse energy, sensing threshold, or stimulation timing intervals, *the* therapy delivery may be restarted by returning to step 460, with continued monitoring of the cardiac activity during stimulation based on measured ARIs. ([0085]; emphasis added).

Klepfer's adjusting the stimulation therapy or temporarily withholding the stimulation therapy does not constitute switching from one stimulation therapy to another stimulation therapy, particularly switching from an ATP therapy to a non-atrial tracking therapy. On the contrary, Klepfer specifically states that "the therapy may be restarted"

after "a temporary withholding of therapy for one or more beats, or after adjusting the stimulation therapy" ([0085]; emphasis added).

Switching from an ATP therapy to a non-atrial tracking therapy in response to detection of lead dislodgement is a concept wholly missing from Klepfer. Klepfer's temporarily withholding or adjusting a stimulation therapy, and then resuming the stimulation therapy, does not account for this concept or even the aspect of switching therapies. For at least this reason, the rejection does not account for all elements of independent claims 1 and 36 and is therefore improper.

Moreover, it is noted that the rejection, as quoted above, cites to Klepfer's disclosure of withholding/adjusting therapy in response to detection of an abnormal beat. Paragraph [0085], cited in support of the rejection and quoted above, temporary withholds or adjusts the therapy "after detecting an abnormal beat" (see steps 480 and 485 of Figure 6). The rejection also cites paragraph [0111], as quoted above. In paragraph [0111], Klepfer disclosures that measured deviations could be due to lead dislodgement (and not a physiologic cardiac issue). Specifically, paragraph [0111] states:

> Factors may exist which cause a change in a measured ARI that is unrelated to a change in activation pattern or origin. Such factors may be lead-related, e.g. lead encapsulation, movement or dislodgement or compromised lead integrity. Therefore, in some embodiments, additional diagnostic methods or parameter monitoring may be performed as a cross-check for verifying that a change in a measured ARI is not due to factors other than changes in activation pattern. In addition or alternatively, the stability of an ARI measurement may be examined to determine if an ARI measurement reflects a transient change, such as in the presence of a premature ventricular contraction or non-sustained arrhythmia, or a sustained change, as might be expected when a lead-related factor has caused the ARI to change.

Klepfer performs this check by "verifying that a change in ARI measured on the monitoring EGM signal is due to a change in activation pattern." ([0112]). Klepfer outlines this check in the flow chart of Figure 12. In this embodiment, "If an abnormal beat classification is made, as determined at decision step 835, the cross-check EGM signal may

be used for verifying that a change in the activation pattern is present and the monitoring ARI measurement is valid." ([0114]). Klepfer further provides that:

> [0115] If, however, a change in the monitoring ARI measurement is not substantiated by a change in the cross-check ARI measurement, or the ARI measurements changes remain stable over a period of time without other evidence of a sustained arrhythmia, as determined at decision step 845, diagnostic tests for evaluating lead-related changes may be performed at step 855. Lead diagnostic tests may include lead impedance measurements or other lead performance tests known in the art. If a lead-related change is identified, as determined at decision step 860, new reference ARIs are preferably acquired by returning to step 805 prior to resuming cardiac activity monitoring. A change in lead impedance may indicate lead shifting or dislodgement, tissue encapsulation or other changes that influence the sensed EGM/ECG signals, thus influencing measured ARIs. The abnormal beat classification made at step 830 may be ignored for arrhythmia detection purposes.

As shown above, Klepfer generates new reference ARI's and ignores the abnormal beat classification in response to detection of the lead condition. This is different from Klepfer's withholding/adjusting therapy in response to detection of an abnormal beat, which is the subject matter of paragraphs [0080] and [0085] cited in support of the rejection. Therefore, it would appear to be improper to consider Klepfer's withholding/adjusting therapy as the response to detection of a lead condition, because Klepfer specifically provides for ensuring that detection of a lead condition is not confused with detection of an abnormal beat. Klepfer's generating new reference ARI's and ignoring an abnormal beat classification in response to detection of a lead condition would not find correspondence with the independent claims.

For each of the reasons discussed above, it is respectfully submitted that the rejection does not account for disabling atrial ATP therapy delivery and delivering a non-atrial tracking pacing therapy in response to measured impedance indicating dislodgement of an atrial lead. As such, the rejection does not account for all elements of independent claims 1 and 36. Reconsideration and withdrawal of the rejection is therefore requested.

It is also submitted that the rejection does not account for all elements of independent claim 20. Independent claim 20 recites in part:

> disabling atrial ATP therapy delivery in response to any of the impedance, capture threshold, and sense amplitude measurements deviating from the impedance, capture threshold, and sense amplitude limits by predetermined impedance, capture threshold, and sense amplitude factors, respectively when the atrial arrhythmia monitoring does not detect atrial arrhythmia; and
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> disabling atrial ATP therapy delivery in response to impedance measurements deviating from the impedance limit by the predetermined impedance factor and disregarding deviations from the capture threshold and the sense amplitude limit for the purpose of disabling atrial ATP therapy when the atrial arrhythmia monitoring detects atrial arrhythmia.

As shown above, claim 20 concerns two different ways of treating information depending on whether atrial arrhythmia is detected, which includes disregarding capture threshold and sense amplitude limit deviations for the purpose of disabling atrial ATP therapy when atrial arrhythmia is detected. It does not appear that the Office Action addresses this subject matter in accounting for claim 20. Reference to claim 20 is made on Pages 2 and 4 of the Office Action, but the discussion spanning pages 2-4 appears to cover other aspects of claim 20 while omitting reference to the above subject matter. It is also noted that other inconsistencies exist in the rejection suggesting that an error was made in putting together the Office Action. For example, a rejection for claims 2, 3, 9-12, 26, 27, 32, 37, 38, and 44-47 is detailed on Page 4 even though these claims were canceled in the Office Action Response of July 13, 2009.

It is respectfully submitted that a *prima facie* case for obviousness for claim 20 cannot be made without addressing all of the subject matter of this claim. (MPEP §2141). The rejection of claim 20 is incomplete and therefore improper. Reconsideration and withdrawal of this rejection is respectfully requested.

Each of claims 4, 6, 13-15, 18, 21, 29, 30, 33, 39-41, 48-50, 53, 55, 58, 60, 63, and 64 depend from one of independent claims 1, 20, and 36, respectively. Independent claims 1, 20, and 36 are not *prima facie* obvious for at least the reason that the rejection fails to

account for all elements of these claims. While no acquiescence is made to the particular rejections of the dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 20, and 36. Therefore, withdrawal of the obviousness-type rejections of claims 1, 4, 6, 13-15, 18, 20, 21, 29, 30, 33, 36, 39-41, 48-50, 53, 55, 58, 60, 63, and 64 and notification that these claims are in condition for allowance is respectfully requested.

To the extent that the current response does not respond to any characterization in the Office Action of the asserted art or of the claimed subject matter, or to any application in the Office Action of the asserted art to any claimed subject matter, it is stated for the record that any such lack of response should not be interpreted as an acquiescence to such characterizations or applications. A detailed discussion of each of the Office Action's characterizations, or any other assertions or statements beyond that provided above is unnecessary in view of the present response. The right to address in detail any such assertions or statements in the future is reserved. It is respectfully submitted that the application is in condition for allowance, timely notification of which is kindly requested.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.014US01) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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